

Message Text

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PAGE 01 STATE 033703

21

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EA-10 EUR-12 NEA-09 OES-05 MED-03

ISO-00 /062 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP:MSBEAUBIEN

DHEW/OIH/MACODDING

AF/RA:JAANDEREGG INFO

EA/RA:CCHAPMAN INFO

NEA/IRN BBMORTON INFO

ARA/NSC-IG:RJBLOOMFIELD INFO

EUR/NSC-IG:JROUSE INFO

----- 025155

R 132231Z FEB 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY BRUSSELS

AMEMBASSY PARIS

AMEMBASSY KINSHASA

AMEMBASSY PORT AU PRINCE

AMEMBASSY TEHRAN

AMEMBASSY ROME

AMEMBASSY TOKYO

AMEMBASSY WELLINGTON

AMEMBASSY MANILA

AMEMBASSY PRETORIA

AMEMBASSY SINGAPORE

AMCONSUL HONG KONG

UNCLAS STATE 033703

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, AS, BE, FR, CG, HA, HK, IR, IT,

JA, NZ, RP, SF, SN, TH, TW, VE

SUBJECT: RECALL OF DEFECTIVE MEDICAL DEVICE

1. FDA ADVISES THAT PHARMASEAL LABORATORIES, 4401 FOXDALE

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PAGE 02 STATE 033703

AVENUE, IRWINDALE, CALIF 91706 IS RECALLING FROM USER LEVEL A

STERILE DISPOSABLE PLASTIC 3-WAY STOPCOCK DEVICE WITH TWO FEMALE LUER SIDE ARMS, ONE MALE LUER SLIP AND A STOPCOCK HANDLE. THE DEVICE IS USED IN I.V. SETUPS, SUCH, ADMINISTRATION OF FLUIDS, BLOOD, AND MEDICATIONS. THE UNITS ARE INDIVIDUALLY ASEPTICALLY PACKAGED IN ENVELOPES AND LABELED AS K-75 STERILE 3-WAY STOPCOCK, PHARASEAL, INC., TOA ALTA, PUERTO RICO, OR LABELED AS TOMAC 3-WAY STOPCOCK, CAT. NO. 17108-010, K-75 MADE IN USA FOR AMERICAN HOSPITAL SUPPLY CORPORATION, EVANSTON, ILLINOIS 60201. INDIVIDUAL ENVELOPES ARE PACKAGED FIFTY TO A BOX.

2. THE FOLLOWING LOT NUMBERS ARE INVOLVED: ALL LOT NUMBERS BEGINNING WITH "H"4" AND ALL LOTS BEGINNING WITH "H3S". THE H REPRESENTS PUERTO RICO PRODUCTION; THE #3 AND #4 REPRESENTS 1973 AND 1974 RESPECTIVELY; AND THE S REPRESENTS THE MONTH OF DECEMBER. CATALOG NOS. ARE AS FOLLOWS:

PHARMASEAL - K-75
AMERICAN HOSPITAL SUPPLY - 17108 - 010 K-75

3. THERE ARE TWO PROBLEMS INVOLVED WITH THE 3-WAY STOPCOCKS:

(1) THE FEMALE LUER PORTS DO NOT PROVIDE A TIGHT CONNECTION FOR APPARATUS CONNECTED TO THEM SO THAT THERE MIGHT BE LEAKS OR DISCONNECTIONS WHICH COULD RESULT IN THE LOSS OF BLOOD, FLUIDS, OR MEDICATIONS BEING ADMINISTERED TO PATIENTS.

(2) PINHOLE LEAKS HAVE BEEN FOUND IN THE BOTTOM OF THE RECESSED PORTION OR WELL OF THE STOPCOCK HANDLE WHICH ALLOWS FLUID TO LEAK OUT WHEN THERE IS POSITIVE PRESSURE IN THE SYSTEM OR NON-STERILE AIR TO BE SUCKED WHEN THERE IS NEGATIVE PRESSURE IN THE SYSTEM.

4. NO DEATHS HAVE OCCURRED BUT SEVERAL INJURIES HAVE BEEN REPORTED.

5. ACTION: POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY ARE FAMILIAR WITH THE DETAILS OF THE RECALL AND IF THEY HAVE RECEIVED THE WARNING LETTER ISSUED BY THE FIRM ON NOVEMBER 23, 1974 RECALLING THE PRODUCT.
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 033703

6. FOREIGN CONSIGNEES, AS FOLLOWS:

MCGAW INDUSTRIES PTY. LTD., P.O. BOX 371, EPPING NSW2121, AUSTRALIA.
BENTLY LABS. 40 TUTA LABS, 332 BURNS BAY ROAD LANE, COBE NSW (NEW SOUTH WALES), AUSTRALIA 2066.
AHS/INTERNATIONAL DIVISION AHSBELGIA, PARC INDUSTRIEL DES,

HAUTS-SARTS 4400, HERSTAL LIEGE, BELGIUM.
UNIVERSITE NATIONALE DU ZAIRE - CLINQUES, UNIVERSITAIRES,
PB123 KINSHASA, ZAIRE.
UNESCO, 7 PLACE DE FONTENOY, 75700 PARIS, FRANCE.
OMINIQUE BAILLY & CO., P.O. BOX 104, PORT AU PRINCE, HAITI.
DON BAXTER LABORATORIES, INC. OF IRAN, P.O. BOX 2856,
TEHERAN, IRAN.
LABORATORI PHARMASEAL, P.O. BOX 467, TRIESTE, ITALY.
S.P.N INC., JAPAN BRANCH, SANKAIDO B 9-13 AKASAKI, 1 CHOME
MINATO-KU, TOKYO 107, JAPAN.
TORAY HOSPITAL SUPPLY, GINZA-OHNO BLDG., CHUO-KU, TOKYO 104,
JAPAN (THROUGH S.P., INC.)
MCGAW ETHICALS, LTD., P.O. BOX 18-069, GLEN INNES, AUCKLAND,
NEW ZEALAND.
MCGAW BAXTER LABS., INC. P.O. BOX 712, MAKATI, RIZAL, MANILA
D-401, PHILIPPINES.
SALTON, UNIVERSITY OF SURGAPORL, KANDONG KERBAN HOSPITAL,
SINGAPORE 8.
M. STABLER PTY, LTD. P.O. BOX 2726, JOHANNESBURG, SOUTH AFRICA
(AND CAPE TOWN).
BANGKOK-SWISS TRADING CO., P.O. BOX 349, BANGKOK, THAILAND.
MING HIWAY TRADING CO., P.O. BOX 3507, TAIPEI, TAIWAN.
AMERICAN HOSPITAL SUPPLY CORP., APARTADO 50950, CARACAS 106,
VENEZUELA.
Y.C. WOOD AND CO., LTD., SOLAR HOUSE, 15TH FLOOR 26A-2RA
DES VOEUX ROAD, HONG KONG. INGERSOLL

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEETING AGENDA, PRODUCTION, INVESTMENTS
Control Number: n/a
Copy: SINGLE
Draft Date: 13 FEB 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE033703
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750054-0108
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750244/aaaabnqs.tel
Line Count: 141
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 02 MAY 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <02 MAY 2003 by RuthemTJ>; APPROVED <20 JAN 2004 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF DEFECTIVE MEDICAL DEVICE
TAGS: ETRD, EIND, TBIO, AS, BE, FR, CG, HA, HK, IR, IT, IEA, SPC-1
To: CANBERRA MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006